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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,928	10/05/1998	NORIO INOMATA	47259-0336	8658
55694 7590 07/05/2007 DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209			EXAMINER BORIN, MICHAEL L	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 07/05/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/171,928

Applicant(s)

INOMATA ET AL.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-11, 21 and 30-35 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 and 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Amendment filed 02/28/2007 is acknowledged. Claims 8-11, 21,30-35 are pending. Claims 8-11, 30-32 remain withdrawn from consideration as being directed to non-elected Groups. Claims 33-35 are under examination. Base claim 33 was amended to address method for decreasing ventricle weight, occurring during "chronic cardiac dysfunction which produces pulmonary congestion" (instead of decreasing heart weight as claimed previously).

Amendment to the claims necessitated the following new updated rejections.

Claim Rejections - 35 U.S.C. § 103.

2. Claims 33,34 are rejected under 35 U.S.C. 103(a) as obvious over Blaine in view of Gomez et al and further in view of Baker et al.

The claims are directed to method for decreasing ventricle weight comprising administering a natriuretic peptide. The patients to be treated are suffering from cardiac hypertrophy which produces pulmonary congestion.

Blaine teaches method of treatment of cardiac hypertrophy using atrial natriuretic peptide (ANP) and fragments thereof. See abstract, summary, col. 3, lines 11-20, and claims 1-8. In particular, the treatment reverses cardiac hypertrophy and reduces heart

weight – see Example 11, col. 4, lines 23-41. Thus, the reference teaches method of reducing heart weight after cardiac hypertrophy.

Blaine does not specifically states that cardiac disfunction produces pulmonary congestion. However, the Blaine reference is not limited to any particular outcome of cardiac disfunction which involves cardiac hypertrophy; rather, the reference teaches that any disorders of altered vascular resistance and/or of electrolyte disbalance can be treated (col. 3, lines 11-20). Applicant argues that Blaine does not teach treatment of cardiac hypertrophy occurring during such chronic cardiac disfunction which produces pulmonary congestion. However, again, the reference is silent about the nature of cardiac hypertrophy and broadly addresses any cardiac hypertrophy. Thus, the disclosure of Blain would motivate one skilled in the art to use natriuretic peptides to treat any cardiac hypertrophy. As for treating cardiac hypertrophy occurring during “chronic cardiac disfunction which produces pulmonary congestion”, both pulmonary congestion and cardiac hypertrophy are common signs of heart failure - see Gomez et al for example (p. 804, first line) – so it would be obvious to one skilled in the art that the method of Blaine generally addressing cardiac hypertrophy will be applicable cardiac hypertrophy occurring during “chronic cardiac disfunction which produces pulmonary congestion” as instantly claimed.

With respect to change in the claim language to address method for decreasing ventricle weight, instead of decreasing heart weight as claimed previously, cardiac hypertrophy is manifested first and foremost in the enlargement of left ventricular – see, for example, Baker et al, abstract. See also demonstration of this effect in Example 2 of

the instant specification. Thus, it would be obvious to one skilled in the art that decrease in heart weight demonstrated in Blaine would indicate reduction in ventricular weight.

Finally, with respect to applicant's argument that measurement of water/body weight is distinguishable from measurement of ventricular weight/body weight in the instant case, Examiner disagrees and points out that these are two alternative ways of measuring reduction in heart hypertrophy, and there is no indication in Blaine reference that cardiac hypertrophy being treated therein is any different from cardiac hypertrophy addressed in the instant claims.

3. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable 33,34 are rejected under 35 U.S.C. 103(a) as obvious over Blaine in view of Gomez et al and further in view of Baker et al as applied to claims 33,34 above, and further in view of Salito et al (Circulation, 76:, 115-124, 1987).

The references as applied as above. With regard to claim 35, BNP is functional equivalent of ANP – see Salito reference, for example, as discussed in applicant's response of 0906/2005, p. 6).

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571)272-0735 . The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Borin, Ph.D.

Primary Examiner

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A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.

mlb